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PTO/SB/21 (09-04)

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<b>TRANSMITTAL FORM</b>  (to be used for all correspondence after initial filing)	Application Number	10/762,566-Conf. #3220	
	Filing Date	January 23, 2004	
	First Named Inventor	Richard Franklin	
	Art Unit	1614	
	Examiner Name	DELACROIX MUIRHE, CYBILLE	
Total Number of Pages in This Submission	6*	Attorney Docket Number	20342/1202529-US1

ENCLOSURES (Check all that apply)		
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SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT			
Firm Name	DARBY & DARBY P.C.		
Signature			
Printed name	Jonathan M. Spenner, Ph.D.		
Date	April 26, 2006	Reg. No.	57,268



Application No. (if known): 10/762,566 - Conf. #3220

Attorney Docket No.: 20342/1202529-US1

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Docket No.: 20342/1202529-US1  
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:  
Richard Franklin

Application No.: 10/762,566

Confirmation No.: 3220

Filed: January 23, 2004

Art Unit: 1614

For: FORMULATION AND METHODS FOR  
THE TREATMENT OF  
THROMBOCYTHEMIA

Examiner: DELACROIX MUIRHE,  
CYBILLE

**FOURTH INFORMATION DISCLOSURE STATEMENT (IDS)**

MS Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

In order to comply with the duty to disclose information under 37 C.F.R. § 1.56, and further to the Information Disclosure Statements filed on September 10, 2004, May 25, 2005, and August 12, 2005, Applicants submit herewith a Fourth Information Disclosure Statement pursuant to 37 C.F.R. §§ 1.97 and 1.98. In particular, Applicants submit herewith a Form PTO/SB/08 (Substitute to Form PTO-1449) listing references USPD1 to USPD12, FPD1 to FPD13, and NPLD1 to NPLD16 for consideration by the Examiner. Copies of listed references FPD1 to FPD13 and NPLD1 to NPLD16 are also submitted herewith. Copies of listed references USPD1 to USPD12 are not provided here since these references are U.S. patents and U.S. published applications. *See*, 37 C.F.R. § 1.98(a)(2)(ii). However, copies of the listed U.S. patents and U.S. published applications will be provided at the Examiner's request.

An English translation is provided for European Patent No. EP 00 21 338. Please note that the claims of EP 00 21 338 are already provided in English in the original document on page 5.





PTO/SB/08a/b (07-05)  
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<b>Substitute for form 1449A/B/PTO</b>  <b>FOURTH INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>			<b>Complete if Known</b>		
			Application Number	10/762,566-Conf. #3220	
			Filing Date	January 23, 2004	
			First Named Inventor	Richard Franklin	
			Art Unit	1614	
			Examiner Name	DELACROIX MUIRHE, CYBILLE	
Sheet	1	of	2	Attorney Docket Number	20342/1202529-US1

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
	USPD1	US-4,837,239	06-06-1989	Benjamin et al.	
	USPD2	US-6,110,471	08-29-2000	Conti et al.	
	USPD3	US-6,297,243	10-02-2001	Groendahl	
	USPD4	US-6,548,529	04-15-2003	Robl et al.	
	USPD5	US-20020004498-A1	01-10-2002	Doherty et al.	
	USPD6	US-20030134861-A1	07-17-2003	Doherty et al.	
	USPD7	US-20030181461-A1	09-25-2003	Lautt et al.	
	USPD8	US-20040014761-A1	01-22-2004	Place et al.	
	USPD9	US-20040087486-A1	05-06-2004	Hanson	
	USPD10	US-20040087546-A1	05-06-2004	Zeldis	
	USPD11	US-20050049293-A1	03-03-2005	Lautt	
	USPD12	US-20050119272-A1	06-02-2005	Lautt et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				
	FPD1	EP-EP0021338	01-07-1981	F. Hoffman-La Roche & Co.		✓
	FPD2	EP-EP0153152	08-28-1985	Syntex (U.S.A.) Inc.		
	FPD3	EP-EP0406958	01-09-1991	Janssen Pharmaceutica N.V.		
	FPD4	WO-WO2001041807	06-14-2001	Virus, Inc.		
	FPD5	WO-WO2003000343	01-03-2003	Virus, Inc.		
	FPD6	WO-WO2003061638	07-31-2003	Diamedica Inc.		
	FPD7	WO-WO2003061648	07-31-2003	Diamedica Inc.		
	FPD8	WO-WO2004012700	02-12-2004	Torrent Pharmaceuticals Limited		
	FPD9	WO-WO2004043336	05-27-2004	Celgene Corporation		
	FPD10	WO-WO2004037262	05-06-2004	Virus, Inc.		
	FPD11	WO-WO2004043464	05-27-2004	Celgene Corporation		
	FPD12	WO-WO2005048979	06-02-2005	Torrent Pharmaceuticals Limited		
	FPD13	WO-WO2005065639	07-21-2005	Torrent Pharmaceuticals Limited		

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	NPLD1	Abe Andes et al., "Inhibition of platelet production induced by an antiplatelet drug, anagrelide, in normal volunteers." Thromb. Haemost., 1984, 52:325-8	
	NPLD2	Argylin Product Monograph, Shire Laboratories, 2003	
Examiner Signature	Date Considered		

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Substitute for form 1449A/B/PTO  <b>FOURTH INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)				<b>Complete if Known</b>	
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				Examiner Name	DELACROIX MUIRHE, CYBILLE
Sheet	2	of	2	Attorney Docket Number	20342/1202529-US1

	NPLD3	Decision on FDA Citizen Petition No. 2004P-0365 by the FDA, April 18, 2005	
	NPLD4	Doherty, "Oral, Transdermal and Transurethral Therapies for Erectile Dysfunction" in Male Infertility and Dysfunction, Ch. 33, 1997	
	NPLD5	European Agency for the Evaluation of Medicinal Products (EMA): Scientific Discussion of European Public Assessment Report (EPAR) Xagrid [http://www.emea.eu.int/humandocs/PDFs/EPAR/Xagrid/136504en6.pdf] European Agency for the Evaluation of Medicinal Products, 2004	
	NPLD6	FDA Citizen Petition No. 2004P-0365 on behalf of Shire US, Inc., August 13, 2004	
	NPLD7	Gaver et al., "Disposition of anagrelide, an inhibitor of platelet aggregation." Clin. Pharmacol. Ther., 1981, 29:381-386	
	NPLD8	Green et al., "Management of the myeloproliferative disorders : distinguishing data from dogma." Hematol. J., 2004, 5 Suppl. 3:S126-132	
	NPLD9	Kelly and Smith, "Pharmacological treatment of heart failure," in Goodman and Gilman, Ch. 34, 1996	
	NPLD10	Mazur et al., "Analysis of the mechanism of anagrelide-induced thrombocytopenia in humans." Blood, 1992, 79:1931-1937	
	NPLD11	Oertel, "Anagrelide, a selective thrombocytopenic agent." Am. J. Health Syst. Pharm., 1998, 55:1979-86	
	NPLD12	Petitt et al., "Anagrelide for control of thrombocytopenia in polycythemia and other myeloproliferative disorders." Semin. Hematol., 1997, 34:51-4	
	NPLD13	Response to FDA Citizen Petition No. 2004P-0365 by Mylan Pharmaceuticals, Inc., September 8, 2004	
	NPLD14	Response to FDA Citizen Petition No. 2004P-0365 on behalf of Barr Laboratories, Inc., October 20, 2004	
	NPLD15	Spencer and Brogden, "Anagrelide. A review of its pharmacodynamic and pharmacokinetic properties, and therapeutic potential in the treatment of thrombocythaemia." Drugs, 1994 47:809-22	
	NPLD16	Trapp et al., "Anagrelide for treatment of patients with chronic myelogenous leukemia and a high platelet count." Blood Cells Mol. Dis., 1998, 24:9-13	

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature		Date Considered	
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